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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,188	07/17/2003	Alex Stenzler	23086-81003	2241
34492	7590	10/07/2005	EXAMINER	
SIDLEY AUSTIN BROWN & WOOD LLP (LAIP GROUP)			LEWIS, AARON J	
555 W. FIFTH ST., SUITE 4000				
LOS ANGELES, CA 90013			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,188

Applicant(s)

STENZLER, ALEX

Examiner

AARON J. LEWIS

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-14 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-14 of prior U.S. Patent No. 6,615,825. This is a double patenting rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1,3,14 are rejected under 35 U.S.C. 102(e) as being anticipated by Zimlich, Jr. et al. ('838).

As to claim 1, Zimlich, Jr. et al. disclose a pulmonary drug delivery device (10) comprising: a hand piece (12) electrically connected to a control unit (60); a cartridge

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(20,24) engagable with the hand piece, the cartridge comprising: a drug reservoir (22), a pump connected to the drug reservoir (col.9, lines 47-54); an electrically chargeable nozzle (32') connected to the pump; a discharge electrode (38); and an information storage element (col.17, lines 57-63), wherein the control unit controls the pump and the electrical charge of the nozzle and discharge electrode in accordance with instructions stored within the information storage element.

As to claim 3, Zimlich, Jr. et al. disclose storage element is programmable (col.15, line 19).

Claim 14 is substantially equivalent in scope to claim 1 (i.e. provides equivalent structure and recites method of using provided structure) and is anticipated by Zimlich, Jr. et al. for the reasons set forth above with respect to claim 1.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2,4-9,11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimlich, Jr. et al. in view of Haver et al. (WO 92/17231).

The difference between Zimlich, Jr. et al. and claim 2 is the control unit including a cartridge reader.

Haver et al., in a pulmonary drug delivery device, teach a control unit having a cartridge reader (57a-n) for the purpose of reading information about the particular

medicament including type of medicament, time interval between doses, number of doses remaining (see abstract).

It would have been obvious to modify the control unit of Zimlich et al. to include a cartridge reader because it would have provided information about the particular medicament including type of medicament, time interval between doses, number of doses remaining as taught by Haver et al..

As to claim 4, Zimlich, Jr. et al. as modified by Haver et al. disclose the information storage element also stores drug identification information.

As to claims 5-9, Haver et al. teach the information storage element also stores drug delivery protocol, dosage information including time between dosages, expiration date for the drug and drug/cartridge identifier (page 10, line 4-page 11, line 9).

As to claims 11-13, the difference between Zimlich, Jr. et al. as modified by Haver et al. and claim 11 is the information storage element comprising a bar code. It would have been obvious to further modify the information storage element of Zimlich, Jr. et al. as modified by Haver et al. to substitute a functionally equivalent electronic data storage element including a bar code, magnetic strip and/or memory chip as an obvious matter of design choice because any one of these data storage chips would function as well as another. Further, applicant has not indicated any criticality for any particular data storage element; therefore, the claimed data storage elements are deemed to be functionally equivalent.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zimlich, Jr. et al. ('838) in view of Mishelevich et al. ('842).

The difference between Zimlich et al. and claim 10 is the information storage element having an RF tag.

Mishelevich et al., in a pulmonary drug delivery device, teach an information storage element comprising an RF tag for the purpose of communicating (via radiofrequency at col.6, line 38) to and from a clinical workstation in the office of a physician for programming and for monitoring compliance.

It would have been obvious to modify the information storage element to include an RF tag because the RF tag would have provided a means for communicating (via radiofrequency at col.6, line 38) to and from a clinical workstation in the office of a physician for programming and for monitoring compliance as taught by Mishelevich et al..

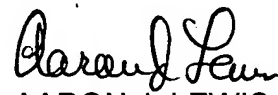
Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant pulmonary drug delivery devices having electrodes for creating an aerosol.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
September 14, 2005